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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC, an Arizona limited liability company, Plaintiff, v. Aesthetic Distribution, LLC d/b/a Olympus Labs, a New Jersey limited liability company, Defendant.	Case No. **COMPLAINT** (Jury Trial Demanded)

For its Complaint against defendant Aesthetic Distribution, LLC d/b/a Olympus Labs ("Olympus"), ThermoLife International, LLC ("ThermoLife") alleges as follows:

NATURE OF THE CASE

1. Plaintiff ThermoLife is a world leader in the use and development of nitrate technology in Dietary Supplements. Supplementation with nitrates has been demonstrated to increase Nitric Oxide (NO) and reduce resting blood pressure. Nitrate supplementation also reduces oxygen consumption during exercise and can enhance exercise tolerance and performance. ThermoLife holds at least 16 patents with more than 450 claims related amino acid nitrate compounds, compositions, and their uses in

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Dietary Supplements and food products. ThermoLife is also the exclusive licensee of a global patent portfolio protecting the use of nitrates and nitrites (separate and apart from amino acids) for increasing athletic performance and increasing endurance. ThermoLife's ingredients are included in the best-selling sports nutrition products in the world.

2. Defendant Olympus competes with ThermoLife and products sourced from ThermoLife in the Dietary Supplement market.

3. Olympus got its start in the Dietary Supplement industry by selling dietary supplements that included illegal synthetic amphetamine-like drug ingredients. Olympus' advertising repeatedly touts the company's history of selling illegal supplements, and even goes as far as to boast that it was the first company to bring "J. Regia" to the market. J. Regia is an abbreviation for "Juglans regia", which is used as a botanical cover for the drug compound known as DMHA, a synthetic amphetamine-like stimulant that the FDA approved for use as a drug in 1946, and is illegal for sale in Dietary Supplements.

4. Olympus has continued to market and sell products that include illegal drugs to unknowing dietary supplement consumers. Olympus' drug products compete directly against the world's top-selling pre-workout product: Cellucor's C4—a pre-workout product fueled by ThermoLife's patented creatine nitrate.

5. In addition to including illegal drugs in their products, Olympus also lies to consumers about many of the other ingredients in its products. As explained further below, many of Olympus' products list natural botanical ingredients on the label, like Juglans Regia extract or Eria Jarensis extract. However, instead of the natural botanical ingredient listed on the label, Olympus' products do not include these plant extracts, for example, there is no Eria Jarensis extract in Olympus products; instead, Olympus' products include synthetic compound known as N,N-Dimethylphenethylamine (N,N-DMPEA) that is, in fact, manufactured in a factory in China.

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6. In addition to selling drugs labeled as Dietary Supplements, Olympus has also falsely marketed, and falsely patent marked its products, claiming its products include "clinically dosed" and "patented" ingredients. One such ingredient is named VASO6. Olympus claims that VASO6 is "patented" and is "clinically proven" to "stimulate[] nitric oxide levels 10x greater than Citrulline." Contrary to these blatantly false claims, VASO6 is not "patented", "clinically-proven", or "clinically studied" for its advertised effects, and VASO6 is not proven to "stimulate[] nitric oxide levels 10x greater than Citrulline."

7. Olympus' business model is based on lies, false marketing, and callous manipulation of the regulatory regime for Dietary Supplements.

8. Olympus' advertising statements are provably false and Olympus is fully aware that its advertising statements are false. In addition to selling drugs falsely labeled as Dietary Supplements, in direct competition with ThermoLife and products sourced from ThermoLife, Olympus continues to unfairly compete with ThermoLife by selling synthetic drug ingredients that it intentionally mislabels as botanicals (which it also falsely claims are included in "clinical doses"), while also intentionally mislabeling other ingredients like VASO6 which Olympus falsely labels as a patented "gallate-enhanced oligomer" that is supplied in a "clinical dose." In fact, all these statements are blatant lies. Olympus is simply unable to compete in the marketplace fairly; its continued and repeated willful false advertising must cease.

9. ThermoLife brings claims for false advertising under 25 U.S.C. § 1125(d), false marking under 35 U.S.C. § 292 and unfair competition against its competitor Olympus. In competition with ThermoLife, Olympus is willfully and intentionally misleading consumers into purchasing Olympus' falsely advertised, falsely marked, misbranded, and adulterated products. Olympus' ill-gotten profits must be disgorged.

PARTIES, JURISDICTION AND VENUE

10. Plaintiff ThermoLife is an Arizona limited liability company with its principal place of business in Phoenix, Arizona.

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11. Olympus is a New Jersey limited liability company with its principal place of business in New Jersey. Olympus markets and distributes Dietary Supplements throughout the United States, including in Arizona. Its interactive website offers for sale and sells the products at issue to Arizona customers and it ships products to such customers.

12. Olympus falsely advertises to Arizona customers and unfairly competes with ThermoLife in the state.

13. Personal jurisdiction exists under Arizona's long-arm statute.

14. The Court has jurisdiction over Plaintiff's federal claims under 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). This Court has jurisdiction over Plaintiff's state law claims based on 28 U.S.C. §§ 1338(b) and 1367.

15. Venue is proper in this district under 28 U.S.C. § 1391(b)-(c), because a substantial part of the events or omissions giving rise to ThermoLife's claims occurred in this district.

16. Venue with respect to Olympus is also proper in this district because Olympus is subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

THERMOLIFE

17. Ron Kramer ("Kramer") founded ThermoLife in 1998. Prior to founding ThermoLife, Kramer opened and operated a Gold's Gym in Santa Cruz, California.

18. In 1998, Kramer founded ThermoLife in order to provide the public with quality proven supplements.

19. ThermoLife currently holds 23 separate and distinct patents that protect its innovative development and use of ingredients in Dietary Supplements and food products.

20. ThermoLife holds at least 16 patents with more than 450 claims related to amino acid nitrate compounds, compositions, and uses in Dietary Supplements and food products.

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21. For example, ThermoLife's U.S. Patent No. 8,178,572 protects and covers "a method for increasing the vasodilative characteristics of amino acids in a human, the method comprising administering orally to the human a pharmaceutically effective amount of an amino acid compound consisting essentially of a nitrate of an amino acid selected from the group consisting of Arginine, Agmatine, Beta Alanine, Citrulline, Creatine, Glutamine, L-Histidine, Isoleucine, Leucine, Norvaline, Ornithine, and Valine."

22. With few exceptions, anytime an amino acid is combined with nitrate(s) and sold and marketed to consumers in a Dietary Supplement, that product relies on ThermoLife's patented technology.

23. ThermoLife's patented creatine nitrate has proven exceedingly popular in the Dietary Supplement market.

24. Creatine is sold in many forms and for decades has been used to promote muscle mass in individuals. Creatine nitrate is a new form of creatine where the creatine molecule is ionically bound to a nitrate ion. Among its other benefits, the bonding of the creatine with the nitrate increases the solubility of the compound, which is beneficial for use in Dietary Supplements.

25. ThermoLife licenses and sells its patented creatine nitrate for use in Dietary Supplement products.

26. Sourced and licensed from ThermoLife, creatine nitrate and other amino acid nitrates supplied by ThermoLife are included in many of the top-selling Dietary Supplements in the world.

27. These ingredients are sought after by consumers of Dietary Supplements looking to gain muscle and increase athletic performance or improve physical appearance. The "Sports Nutrition" category of Dietary Supplements caters to this subset of Dietary Supplement consumers.

28. As just one example, ThermoLife's creatine nitrate is the marquee ingredient in the world's top-selling pre-workout product: Cellucor's C4.

29. As a result of the popularity of ThermoLife's nitrates in the Dietary Supplement market, ThermoLife's business is tied to the performance of products that rely on ThermoLife's patented ingredients and technologies.

30. ThermoLife is harmed when consumers are misled into purchasing any falsely advertised product that competes with any product that contains ingredients that are sourced from ThermoLife and/or technology that is licensed from ThermoLife.

31. ThermoLife has an identifiable economic interest in the Dietary Supplement market, including the Sports Nutrition segment.

OLYMPUS

32. Olympus sells and advertises Dietary Supplements over the internet, through its own website and websites of online retailers whose business is marketing and selling Dietary Supplements in the Sports Nutrition Market. Olympus also sells its products to wholesalers and in brick-and-mortar stores. Olympus competes directly with ThermoLife and the licensees of ThermoLife's patented ingredients and technology in the Dietary Supplement market.

33. As explained below, however, Olympus' competition is unfair and illegal. Instead of using ingredients that comply with the regulatory regime, Olympus consistently adds ingredients that have been classified as drugs to its products—an act that is strictly illegal under the regulatory regime. In addition, Olympus makes blatantly false and unfounded claims regarding its ingredients and its products.

34. Olympus' false advertising is willful, and its false statements have caused ThermoLife competitive injury. Any profits that Olympus earned as a result of its intentional false advertising is ill-gotten gains and must be disgorged.

REGULATION OF DIETARY SUPPLEMENTS

35. While Olympus' false statements are readily identifiable as false on their own, a brief summary of the rules and regulations that govern the sale and marketing of Dietary Supplements is informative.

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36. Congress determined which ingredients can be used in Dietary Supplements when it passed The Dietary Supplement Health and Education Act of 1994 ("DSHEA").

37. In 21 U.S.C. § 321(ff), DSHEA defines "Dietary Supplements" as follows:

> The term "Dietary Supplement"—
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
> (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
> (2) means a product that—
> (A) (i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or (ii) complies with section 350(c)(1)(B)(ii) of this title;
> (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
> (C) is labeled as a Dietary Supplement; and
> (3) does—
> (A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a Dietary Supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a Dietary Supplement under the conditions of use and dosages set forth in the labeling for such Dietary Supplement, is unlawful under section 342(f) of this title; and
> (B) not include—
> (i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or
> (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization

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> marketed as a Dietary Supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

38. Because there is no pre-approval process for Dietary Supplements, prior to selling any product as a Dietary Supplement it is the seller's responsibility to ensure that the product complies with Section 321(ff).

39. Accordingly, 21 U.S.C. § 321 (ff)(3)(B)(i) specifically prohibits the use of any article approved as a drug from being included in a Dietary Supplement, and 21 U.S.C. § 321(ff)(3)(B)(ii) specifically prohibits the use in Dietary Supplements of "any article authorized for investigation as a new drug, for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."

40. As the FDA has explained many times, declaring a product a "Dietary Supplement" that includes ingredients that are not in compliance with Section 321(ff) "causes product[s] marketed as Dietary Supplements to be misbranded under 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false and misleading in any particular."

41. While 21 U.S.C. § 321(ff) defines what type of ingredients can and cannot be included in a "Dietary Supplement", 21 U.S.C. § 331 describes prohibited acts.

42. 21 U.S.C. § 331(a) prohibits introduction or delivery for introduction interstate commerce of any food, or drug, that is adulterated or misbranded.

43. 21 U.S.C. § 331(ll) bars the sale of any food to which a drug is added in interstate commerce that includes any approved drug, or any ingredient upon which a "substantial clinical investigation has been instituted and made public." Products that contain a substance that has been authorized for investigation as a new drug are outside the definition of a dietary supplement. 21 U.S.C. § 321(ff).

44. And, as discussed below, products that are adulterated under 21 U.S.C. § 350(b) are considered unsafe and prohibited from being sold in interstate commerce under 21 U.S.C. § 331(v).

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45. The FDA has declared time and time again, under 21 U.S.C. § 350b, Dietary Supplements are deemed "adulterated" under 21 U.S.C. § 342(f), and not legal for sale, unless all of the ingredients included in the Dietary Supplement meet one of the following two requirements:

> (i) the dietary supplement contains only dietary ingredients that have been present in the food supply [since 1994] as an article used for food in a form in which the food has not been chemically altered; or
>
> (ii) there is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

46. As the FDA has explained in numerous warning letters:

> In the absence of a history of use or other evidence of safety establishing … when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, [a Dietary Supplement] is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)].

47. The FDA's website warns customers about the prevalence of "Fraudulent Dietary Supplements:"

> Federal regulators continue to warn consumers about tainted, dangerous products that are marketed as Dietary Supplements. These fraudulent products can cause serious injury or even death.

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> The Food and Drug Administration (FDA) has found nearly 300 fraudulent products—promoted mainly for weight loss, sexual enhancement, and bodybuilding—that contain hidden or deceptively labeled ingredients, such as
>
> - the active ingredients in FDA-approved drugs or their analogs (closely-related drugs)
> - other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients
>
> "These products are masquerading as Dietary Supplements—they may look like Dietary Supplements but they are not legal Dietary Supplements," says Michael Levy, director of FDA's Division of New Drugs and Labeling Compliance. "Some of these products contain hidden prescription ingredients at levels much higher than those found in an approved drug product and are dangerous."
>
> FDA has received numerous reports of harm associated with the use of these products, including stroke, liver injury, kidney failure, heart palpitations, and death.

48. As explained below, Olympus blatantly disregards this regulatory regime.

49. The products Olympus sells, identified in this complaint, are specific examples of the "Fraudulent Dietary Supplements" that the FDA has warned consumers about. Olympus falsely advertises these products as Dietary Supplements or lies about the source of the ingredients, their efficacy, and their patent status. Five of these falsely advertised products (Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r) contain a drug, DMHA, that has serious side effects and/or poses a significant risk even when taken by healthy individuals, yet Olympus' false advertising of these illegal, misbranded drug products as "Dietary Supplements" leads consumers to believe that these products only contain ingredients that are safe, natural, and legal. They do not.

50. In other products, Olympus simply lies about its ingredients claiming them to be "clinically dosed", "clinically proven", "sourced from botanicals", and "patented", when they are not.

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51. In all cases outlined here, Olympus falsely advertises its products and unfairly competes with ThermoLife – Olympus should be disgorged any profits earned from this unfair activity as it is ill-gotten-gains.

OLYMPUS' DMHA PRODUCTS

52. Olympus' website includes a "disclaimer" page. The disclaimer included on that page states: "None of the statements made on this website have been reviewed by the Food and Drug Administration."

53. In addition to this disclaimer on its website, every single product that Olympus ships and sells includes a disclaimer on its label. That disclaimer states: "These statements have not been evaluated by the Food and Drug Administration."

54. Directly contrary to Olympus' disclaimers, at least five of the products that Olympus has sold include an ingredient that is not legal for sale in dietary supplements; these products contain DMHA,[1] which the FDA has evaluated and determined to be a drug. Nonetheless, Olympus has sold products that include DMHA, blatantly lying to consumers on every bottle and on every webpage claiming the FDA has not examined DMHA and made this determination.

55. Olympus markets and sells five products that include an ingredient that it labels as "Juglans Regia Extract" or "J. Regia." Contrary to what is listed on the labels of Olympus's products there is no plant material from Juglans Regia in any of Olympus's products. Instead the products contain a synthetic amphetamine-like drug ingredient more commonly called DMHA, which is falsely labeled as J. Regia Extract or Juglans Regia Extract.

56. Juglans Regia Extract is a botanical name that Olympus uses to trick consumers and regulators into believing that this ingredient is a plant extract, instead of the synthetic drug compound DMHA. Juglans Regia is a species of walnut tree

[1] Olympus doesn't list DMHA on its products' labels. Instead, it lists a botanical cover (as discussed in paragraphs 75-80). This means that customers cannot even make an informed decision about the products they purchase and consumer and they are unknowingly ingesting a drug with serious side effects.

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indigenous to Southwest China and the Himalayas. The "Juglans Regia extract" ingredient included in Olympus' products is not sourced from walnut trees, it is a synthetic amphetamine-like drug compound manufactured in a factory.

57. In a YouTube video that Olympus uses to market and sell its products, the owner of Olympus, Mobi Khawaja, repeatedly touts J. Regia, stating "we brought J. Reg into the market." Astonishingly, Olympus claims that other Dietary Supplement companies essentially copied Olympus' formulations, by including J. Regia; Olympus actually boasts about the fact that it brought an illegal drug, disguised as a botanical, to the Dietary Supplement market and views it as something that consumers should "give credit [for]."

58. Olympus includes Juglans Regia Extract (DMHA) in five of its products: Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r. These products compete directly with products that are sourced from ThermoLife, including Cellucor's top-selling pre-workout: C4.

59. Directly contrary to Olympus' advertising, marketing, and sale of Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r, these products are not Dietary Supplements.

60. The FDA approved DMHA as a prescription drug in 1946.

61. The drug company Smith, Kline, and French introduced DMHA as the active ingredient in the Eskay® Oralator inhaler.

62. Because of DMHA's prior extensive use as an approved drug, it has several known potential serious side effects, including: Insomnia, Headaches, Shortness of Breath, Panic Attacks, Tremor, Increased Blood Pressure), Increased Heart Rate, Increased Rate Pressure Product (Cardiac Hemodynamic Stress), Tachycardia, Cardiac Dysrhythmia (Irregular Heartbeat), Chest Pain, Heat Stroke, Heart Attack, Cerebral Hemorrhage (Stroke), Acute Liver Injury and Failure, Rhabdomyolysis, and Renal Injury.

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63. The FDA has approved DMHA as a "drug." As such, DMHA does not meet the definition of a dietary ingredient and can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient DMHA on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (DMHA) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (DMHA) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists DMHA as a dietary ingredient in a Supplement Facts Panel is both false and misleading and is, therefore, misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient DMHA is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because DMHA (even if it could be a Dietary Ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include the drug DMHA, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded." Furthermore, because DMHA is "adulterated" under 21 U.S.C. § 350b, any product that contains DMHA (like Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r) is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because DMHA is an approved drug, for which substantial clinical trials have been conducted and made public, it can never be a dietary ingredient under 21 U.S.C. §§ 321(ff)(3)(B)(i) and 321(ff)(3)(B)(ii). For this reason as well, any product (like Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r) that includes DMHA is also prohibited for sale in interstate commerce as a Dietary Supplement under 21 U.S.C. § 331(ll), which prohibits "the introduction or

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delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."

64. At bottom, any Dietary Supplement that includes DMHA cannot reasonably be expected to be "safe" because DMHA is a prescription drug and, by law, a drug is not a safe Dietary Ingredient. Olympus' labels and advertising, falsely represents to consumers that the statements made on Re1gn's, I Am Suprem3 Black Magic's, Bloodshed's, Conqu3r's, and Elix1r's labels and in the advertising for these products have not been evaluated by the FDA. In truth, however, the FDA has evaluated DMHA and approved DMHA as a drug, which excludes DMHA from the legal definition of a Dietary Ingredient as per 21 U.S.C. § 321(ff). Accordingly, products labeled as Dietary Supplements that contain the drug DMHA are not safe, and not legal for sale as Dietary Supplements.

65. ThermoLife has suffered competitive injury as a result of Olympus' willful false advertising of Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r as Dietary Supplements.

66. By including DMHA (a drug) as an ingredient in Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r and marketing these products to unknowing consumers as a Dietary Supplement, Olympus has created a serious health risk to consumers. Products that include DMHA are not safe and products that contain DMHA are illegal for sale as Dietary Supplements. Motivated by greed, Olympus made the conscious decision to profit from its false marketing of the DMHA products identified herein. To do so, Olympus has made false and material representations to consumers regarding DMHA and intentionally misled consumers to believe that the ingredient DMHA: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

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67. Making matters worse, Olympus advertised these products as "clinical dosed." In fact, Olympus' website claims its products are "CLINICALLY DOSED FORMULAS YOU CAN TRUST."

68. Also, Olympus' products claim on the product label that they use "Clinical Doses."

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69. The term "clinical dose" suggests that the DMHA (a drug) was tested by professionals for safety and efficacy as used in the Olympus product.

70. Olympus has not "clinically tested" DMHA for its intended use in Olympus' products.

71. In approving DMHA as a drug, the FDA approved it as a nasal inhaler.

72. There have been no clinical studies of DMHA for oral human consumption as a stimulant or weight loss substance: the uses falsely advertised by Olympus.

73. Therefore, Olympus has also falsely advertised these products as "clinically dosed"; misleading consumers regarding the efficacy and safety of DMHA in the Re1gn, I Am Suprem3 Black Magic, Bloodshed, Conqu3r, and Elix1r products.

74. Accordingly, Olympus' intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products, which contain the drug ingredient DMHA, should never have been in the marketplace nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

OLYMPUS' FALSE MARKETING OF SYNTHETIC INGREDIENTS AS BOTANICALS

75. In order to hide the inclusion of drugs, like DMHA, and synthetic compounds, like N,N-Dimethylphenethylamine (N,N-DMPEA), in its products, Olympus falsely labels exotic and/or obscure botanical ingredients in the supplement facts panels of the products it sells. However, the exotic and/or obscure botanical ingredients are not actually included in the product. The botanical names are only listed to hide the presence of illegal and synthetic drug ingredients. This deceptive practice has become known as "botanical covers."

76. Dishonest Dietary Supplement companies use botanical covers because consumers favor natural, not synthetic, ingredients, and also botanical covers make it difficult for the FDA to know that drug ingredients are actually in the product.

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77. In addition to Juglans Regia Extract (which, as explained above, is a botanical cover for the drug DMHA), Olympus' Re1gn, I Am Suprem3 Black Magic, Bloodshed products all falsely list Eria Jarensis extract as an ingredient on the products labels.

78. Eria Jarensis is a natural botanical ingredient, which as stated above is listed on the label of Olympus' Re1gn, I Am Suprem3 Black Magic, Bloodshed products, but these products do not include any plant extracts from Eria Jarensis, Eria Jarensis extract is used as a botanical cover, meaning that instead of including this plant extract, Olympus instead includes a synthetic compound known as N,N-Dimethylphenethylamine (N,N-DMPEA).

79. N-Phenethyl Dimethylamine is a stimulant classified as a Neuromodulator on the Central Nervous system. Olympus' Re1gn, I Am Suprem3 Black Magic, Bloodshed product labels all fail to inform consumers that these products all contain N-Phenethyl Dimethylamine.

80. Olympus' willful false advertising of these products that include Juglans Regia Extract (which, as explained above, is a botanical cover for DMHA), and Eria Jarensis extract (which, as explained above is a botanical cover for N-Phenethyl Dimethylamine) tricks consumers and regulators, causing consumers to purchase products that they believe contain natural botanical compounds, when they in fact include drugs and synthetic compounds, and causing regulators to look the other way if they see only botanical ingredients listed on the label. If Olympus disclosed that these products contained drugs and synthetic compounds, consumers would be less likely to purchase these products and they would, instead, purchase products sourced from ThermoLife. Olympus' profits earned selling products that are misbranded with botanical covers is ill-gotten gains and must be disgorged.

OLYMPUS' FALSE MARKETING AND MARKING OF VASO6 PRODUCTS

81. In addition to falsely marketing products that include drugs labeled as Dietary Supplements and botanical compounds that are actually syntenic stimulants,

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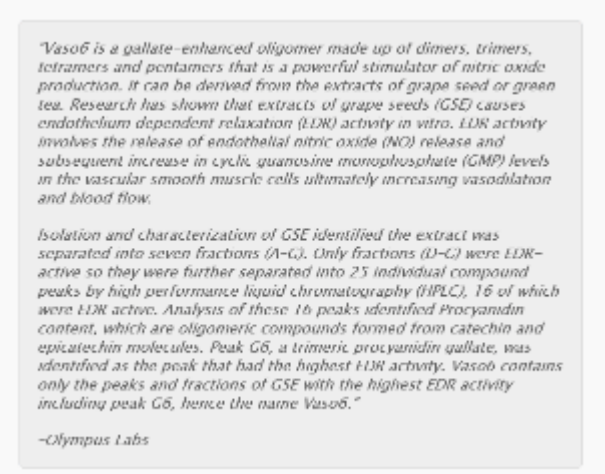
Olympus is also falsely marketing and falsely patent marking all of its products that include the ingredient VASO6.

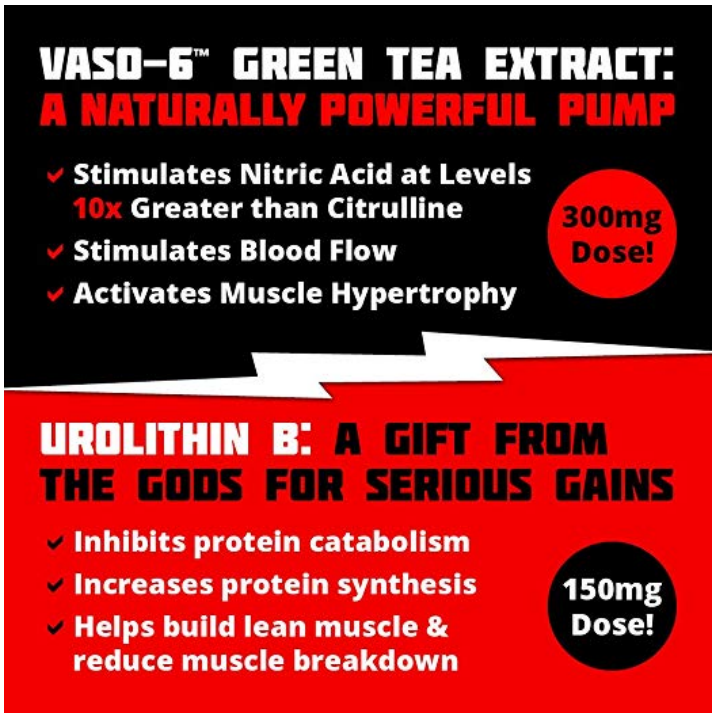
82. Olympus claims to be the first Dietary Supplement to market and sell products that included VASO6.

83. Olympus currently markets and sells four products that include VASO6: Re1gn, I Am Suprem3 Black Magic, Ep1logue, and Massacr3.

84. Olympus' marking for these products claims that VASO6:



85. Olympus' advertising also includes the following black and red graphic:



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86. Additionally, as explained above, Olympus marks each of its products that include VASO6 as including "clinically dosed" formulas.

87. And Olympus marks these products as practicing two patents: U.S. Patent No. 6,706,756 and U.S. Patent No. 7,132,446 B1

88. In addition to marking its products with two patent numbers, Olympus' claims I Am Supreme Black Magic and Re1gn products are covered by 5 patents. I Am Supreme Black Magic state on the labels that the products include five patented ingredients. This is blatantly false.

89. Furthermore, on the Supplement Facts panel included on each of the product labels, Olympus lists the VASO6 product as follows:

90. Once again this is blatantly false. VASO6 is not "Galate-Enhanced Oligomers." VASO6 is green tea extract. Olympus' label falsely lists this ingredient directly on the product label.

91. Here, Olympus lists VASO6 is listed as "Gallate-Enhanced Oligomers", but the common name for VASO6 is not Gallate-Enhanced Oligomers, it is green tea

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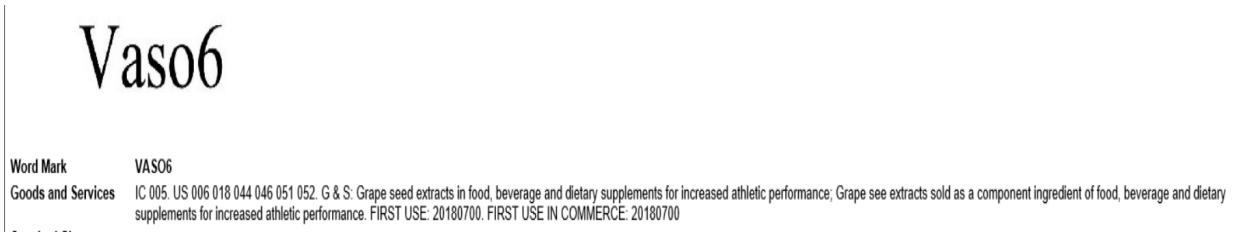
extract. FDA regulations state ingredients must be listed as their common name, here VASO6 is falsely labeled as Gallate-Enhanced Oligomers to fool consumers about the true nature of the ingredient. In fact, because "Gallate-Enhanced Oligomers" is not an ingredient it would be hard to know what VASO6 really is, but if one were to try and identify the ingredient from the label it is logical to check the USPTO for a description of the VASO6 trademark. The USPTO identifies VASO6 as grape seed extract, not green tea extract.[2] Below is the description of VASO6 filed with the USPTO:


Vaso6

Word Mark	VASO6
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Grape seed extracts in food, beverage and dietary supplements for increased athletic performance; Grape see extracts sold as a component ingredient of food, beverage and dietary supplements for increased athletic performance. FIRST USE: 20180700. FIRST USE IN COMMERCE: 20180700

92. A company named Compound Solutions, Inc. supplies and markets VASO6 as an ingredient for use in Dietary Supplements.

93. Like Olympus, Compound Solutions, Inc. claims VASO6 practices U.S. Patent No 6,706,756. But, even Compound Solutions, the supplier of VASO6, does not claim that VASO practices the U.S. Patent No. 7,132,446B1 ("the '446 Patent"), because it doesn't. The '466 Patent protects various uses of a compound comprising "epicatechin-galloyl-epicatechin-gallate (B2-di-gallate)." To practice any claims of the '466 Patent "epicatechin-galloyl-epicatechin-gallate (B2-di-gallate)" is necessary. VASO6 does not include this compound; accordingly, VASO6 cannot possibly practice this patent. Likewise, none of Olympus' products include this compound, so none of Olympus' products can possibly practice the '466 Patent.

94. VASO6 also does not practice the '756 Patent either. The '756 Patent discusses and protects various uses of "isolated procyanidin c1-gallate" and "isolated procyanidins having a preponderance of (−)-epicatechins." The "isolated procyanidin c1-gallate" and "isolated procyanidins having a preponderance of (−)-epicatechins"

[2] Listing VASO6 as "Gallate-Enhanced Oligomers" in the Supplement Facts Panel when the ingredient is really "green tea" causes the product to be misbranded and prohibited for sale in interstate.

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discussed in the study and referenced in the '756 Patent, were obtained from "grape seed extracts."

95. As the makers of VASO6 readily acknowledge, VASO6 is a form of green tea extract, not grape seed extract.[3]

96. ThermoLife recently obtained a sample of VASO6 and had it independently tested. Those tests revealed that VASO6 is nothing but common green tea extract; it does not contain "isolated procyanidin c1-gallate" or "isolated procyanidins having a preponderance of (−)-epicatechins." Without either "isolated procyanidin c1-gallate" or "isolated procyanidins having a preponderance of (−)-epicatechins", VASO6 cannot possibly practice the '756 Patent. Thus, contrary to Olympus's advertising, VASO6 is not "a patented nitric oxide booster."

97. Furthermore, the alleged effects noted in the patent from the "isolated procyanidin c1-gallate" and "isolated procyanidins having a preponderance of (−)-epicatechins" (that was found in grape seed extract, not green tea), was observed in dead rat heart tissue, not in humans.

98. No clinic has evaluated the dosages of VASO6 used in Olympus's products to be equal to the effect of vasodilation effect of grape seed extract on dead rat heart tissue.

99. Moreover, there is no known study comparing the effect of "isolated procyanidin c1-gallate" and "isolated procyanidins having a preponderance of (−)-epicatechins" that was observed in the dead rat heart tissue to human subjects (either dead or alive). Nor are there any studies analyzing the bioavailability of "isolated procyanidin c1-gallate" or "isolated procyanidins having a preponderance of (−)-epicatechins" in humans to achieve the effects observed in the dead rat heart tissue in the study cited in the '756 Patent. Therefore, even if VASO6 did contain "isolated

[3] As part of their scheme to defraud consumers and steal sales from reputable companies like ThermoLife and companies that license ThermoLife's top-selling ingredients, despite admitting that VASO6 is a form of green tea extract, Compound Solutions' registered trademark, U.S. Reg. No. 5681256, for VASO6 actually describes the compound as "grape seed extract." As explained above, what Compound Solutions markets as VASO6 is not "grape seed extract."

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procyanidin c1-gallate" and "isolated procyanidins having a preponderance of (−)-epicatechins" (which is does not) the effects these compounds on humans would be unknown, NOT "clinically proven."

100. Furthermore, there are no clinical studies on humans showing that VASO6 has any of the effects Olympus (or Compound Solutions) attributes to it, or that Olympus includes an effective dose for the intended use as a vasodilator. In fact, what clinical data that does exist on the compounds actually found in VASO6 indicates that the compounds have no effect on blood flow at all, or actually cause vasoconstriction, not vasodilation; this is the exact opposite effect from what VASO6 is alleged to be patented for, "clinically proven" to do, and marketed to provide.

101. There are no available clinical studies demonstrating the effects of VASO6 exhibiting the advertised effects in humans and VASO6 is not "clinically dosed."

102. Olympus falsely advertises Re1gn, I Am Suprem3 Black Magic, Ep1log, and Massacr3 as clinically dosed to add the illusion of validity and efficacy to its products.

103. Accordingly, there is no evidence supporting Olympus' claim that VASO6 is included in a "clinical dose." Olympus' claims are blatantly false.[4]

104. In sum, Olympus built its brand by marketing pre-workout products that provided enhanced energy and focus, through the inclusion of a synthetic illegal amphetamine-like drug substance named DMHA. Deceiving consumers, Olympus advertises this drug ingredient as a natural botanical, when it was in fact it is an illegal synthetic drug ingredient made in a factory. Now Olympus is using the brand name that it built selling products that included illegal drugs, to market and sell new products that include VASO6. Just as Olympus did with J. Regia (which was really DMHA), Olympus is now mislabeling VASO6 as "gallate-enhanced oligomer" when the ingredient is really green tea extract. With VASO6 there is simply no support for

[4] Olympus has also indicated that it will soon start selling two additional VASO6 products: "Levels" and "No Mercy" These products are falsely marketed and marked even before they are sold.

Olympus' ridiculous marketing claims that this ingredient: (1) is "patented"; (2) is "clinically dosed"; (3) has 10x the vasolidilative effects of Citrulline; and (4) it is "powerful stimulator of nitric oxide production." Olympus' marketing is all based on lies. It cannot compete with ThermoLife and products that include ThermoLife's patented ingredients, so it has knowingly and willfully sold drugs labeled as dietary supplements, and falsely advertised and falsely patent marked it products. There is no legal justification that will allow Olympus to keep any of the profits that it has wrongfully earned by tricking consumers; Olympus' ill-gotten gains must be disgorged.

OLYMPUS' PRODUCTS ARE MISBRANDED

105. Olympus markets all of its products as "Dietary Supplements."

106. Congress determined which ingredients can be used in dietary supplements when it passed The Dietary Supplement Health and Education Act of 1994 ("DSHEA").

107. DSHEA regulates the manufacture labeling and sale of Dietary Supplements.

108. Because dietary supplements are not reviewed and approved by the Food and Drug Administration ("FDA") prior to being sold to consumers, every manufacture of dietary supplements is required to ensure that all of its products comply with DSHEA.

109. DHSHEA (21 U.S.C.) § 343(a) sates that a product is "misbranded" "if … it's labeling is false or misleading in any particular … ."

110. Olympus' products identified herein all include labels that are "false or misleading in any particular." As explained above, these products include botanical covers (instead of the drug or synthetic compounds actually found in the products). Moreover, Re1gn, I Am Suprem3 Black Magic, Ep1logue, and Massacr3 all list VASO6 as "Galate-Enhanced Oligomers" on the label when it is really green tea extract (with a trademark that says its grape seed extract) and, furthermore, falsely claim on the labels that VASO6is patented and clinically dosed.

111. Accordingly, these products are all "misbranded."

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112. 21 U.S.C. § 331(a) prohibits introduction in interstate commerce of any food, or drug, that is misbranded.

113. Because all of the products identified herein are misbranded, Olympus is prohibited from selling these products as Dietary Supplements in interstate commerce. Olympus falsely advertises each of these products as Dietary Supplements, misleading consumers.

114. Olympus has willfully and intentionally deceived consumers by selling misbranded and prohibited products and its ill-gotten gains earned from this illegal activity must be disgorged.

FIRST CLAIM FOR RELIEF

(Lanham Act § 43(a))

115. Plaintiff realleges and incorporates herein by reference each and every allegation of this Complaint as is fully set forth herein.

116. Olympus uses, offers for sale, and sells the products at issue in interstate and foreign commerce and has caused the false statements alleged herein to enter interstate and foreign commerce.

117. In connection with any goods or services, Olympus has used one or more words, terms, names, symbols, or devices, alone or in combination thereof, as well as any false designations of origin, false or misleading descriptions of fact, or false or misleading representations of fact in commercial advertising or promotion, and it misrepresents the nature, characteristics, qualities, or geographic origin of its or another person's goods, services, or commercial activities.

118. As alleged above, Olympus has made false statements of fact in commercial advertisements about the products sold on its website, including the false statements identified above.

119. Olympus' deception is material and made in bad faith for the purpose of influencing and deceiving the market, the public, consumers, potential customers and

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competitors. The deception is likely to influence the purchasing decisions of the public for whom it was intended and others.

120. ThermoLife has suffered a commercial injury to its reputation or sales, which was directly and proximately caused by Olympus' false statements and other acts as alleged above.

121. ThermoLife's injury is competitive, i.e., harmful to the ThermoLife's ability to compete in the Dietary Supplement market.

122. By reason of Olympus' statements and conduct, it has willfully violated § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and ThermoLife has suffered, and will continue to suffer damage to its business, reputation and good will and has lost sales and profits that ThermoLife would otherwise have made.

123. ThermoLife's Lanham Act claim does not seek to enforce the provisions of DSHEA through private action. Neither DSHEA nor the Federal Food, Drug and Cosmetics Act preclude a claim under § 43(a) of the Lanham Act. Further, the FDA has already addressed the legality of the ingredients included in the products at issue in here; the FDA declared that the products identified above are improperly marketed as Dietary Supplements and that those products include materials that are classified as drugs. To the extent any claim ThermoLife has asserted mentions the DSHEA, it is in relation to Olympus' violations of DSHEA that have been affirmed by the FDA. ThermoLife seeks to hold Olympus liable for misleading consumers about the products it sells by informing consumers that the FDA had not evaluated the statements made about the ingredients in the products identified above; when, in fact, the FDA has determined that the ingredients in the products listed are drugs, illegal for use in Dietary Supplements. Olympus makes affirmative false statements related to these products by labeling them as Dietary Supplements and implying that they are "legal", "natural", and "safe."

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SECOND CLAIM FOR RELIEF

(Common Law Unfair Competition)

124. Plaintiff realleges and incorporates herein by reference each and every allegation of this Complaint as is fully set forth herein.

125. As alleged above, Olympus has made false statements of material fact in commercial advertisements about the products sold on its website, including, but not limited to, the false statements identified above.

126. Common law unfair competition prevents business conduct that is contrary to honest practice in commercial matters, including deception.

127. ThermoLife has been injured as a result of Olympus' false statements.

128. ThermoLife has suffered a commercial injury based upon a misrepresentation by Olympus.

129. ThermoLife's injury is competitive, *i.e.,* harmful to the ThermoLife's ability to compete in the Dietary Supplement market.

130. As alleged above, ThermoLife's unfair competition claim does not seek to enforce the Federal Food Drug and Cosmetics Act and DSHEA through private action relating to the misbranding of food through false or misleading labeling.

131. ThermoLife has been irreparably harmed by Olympus' acts of unfair competition and it has suffered damages in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF

False Marking – 35 U.S.C. § 292

132. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if fully set forth herein.

133. Defendant knowingly and intentionally marked upon, affixed to, or used in advertising in connection with its Massacr3 product with patent numbers the Olympus knows the product does not practice.

134. Additionally, Olympus has knowingly and intentionally marked upon, affixed to, or used in advertising in connection with its I Am Supreme Black Magic product the claim that this product practices five separate patents. It does not.

135. Each false marking by Olympus identified in this Complaint is likely to discourage or deter persons and companies from commercializing competing products or pursing research and development of competing products and or related products, which injures ThermoLife and the public by stifling competition and increasing the costs of goods.

136. As a direct competitor of Defendant in the sale of products that contain patented ingredients and technology to increase vasodilation, ThermoLife has also suffered a competitive injury as a result of Defendant's violation of 35 U.S.C. § 292.

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JURY TRIAL DEMAND

1. Plaintiff requests a trial by jury on all aspects of the Complaint.

PRAYER FOR RELIEF

WHEREFORE, ThermoLife demands judgment against defendants Olympus as follows:

A. For an award disgorging any and all monies earned by Olympus in connection with the sale of the products identified above;

B. For an award of compensatory and/or restitutionary damages in favor of ThermoLife in an amount to be proven at trial;

C. For an award of treble damages under 15 U.S.C. §§ 1117, 1125(a);

D. For an award of ThermoLife's attorneys' fees and costs under 15 U.S.C. § 1117, A.R.S. § 13-2314.04, and any applicable law;

E. Finding that Defendant falsely marked its Kraken Pre-Workout and Kraken Pump Non-Stimulant Pump Pre-Workout in violation of 35 U.S.C. § 292;

F. For an award of ThermoLife's damages, treble damages, and attorneys' fees under 18 U.S.C. § 1961 *et seq.*;

G. For prejudgment interest on any liquidated sum determined to be due Plaintiff;

H. For post-judgment interest on any judgment;

I. For punitive damages in an amount sufficient to deter Olympus from future wrongful and outrageous conduct;

J. An Order permanently enjoining, Olympus and all those persons in active concert or participation with them, from making false statements on the internet about their products and an order requiring Olympus and those acting in concert or participation with them to remove the false statements from the internet regarding Olympus' products; and

K. For such other and further relief as the Court deems just and proper.

DATED this 27th day of March, 2019.

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